510(k) SUMMARY

K101586

SUBMITTER: Sorin Group Italia S.r.l.
86, Via Statale 12 Nord
41037 Mirandola (MO) Italy

CONTACT PERSON: Luigi Vecchi
Phone: 011 39 0535 29811
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OCT 5 2010

DATE PREPARED: June 3, 2010

DEVICETRADE NAME: XTRA

COMMON NAME: Autotransfusion System

CLASSIFICATION NAME: Apparatus, Autotransfusion

PREDICATE DEVICE: Dideco ELECTA K020647

DEVICE DESCRIPTION:
XTRA Autotransfusion System consists of hardware and disposables. It is the next generation of the Sorin autotransfusion device family. The main elements of the hardware include the centrifuge, blood pump, automatic clamps, control and monitoring sensors, and an user interface (display panel and keyboard).
The main modifications to the disposables are the elimination of the bowl snap on bayonet fitting system to fix the device into the centrifuge, the elimination of the silicone coating inside the bowl and the newly designed system that allows the set up of the disposable set to simplify the installation of disposable.

INDICATION FOR USE:
The XTRA Autotransfusion System is indicated for intraoperative and postoperative recovery of blood, washing of the processed blood and preoperative sequestration (with indirect patient connection). Typical clinical applications of autotransfusion include the following surgical specialties: Cardiovascular, Orthopedics, Thoracic, Transplant Surgery, Emergency (Trauma), Neurosurgery, Obstetrics and Gynecology, and Urology.

TECHNOLOGICAL CHARACTERISTICS:
Sorin makes the claim of substantial equivalence to cited predicates based on intended use, indications for use, technological characteristics, and operational characteristics.

Sorin Group Italia Srl believes that the XTRA Autotransfusion System is substantially equivalent to the Dideco ELECTA and to other currently marketed automated autotransfusion devices, that any differences are minor, and raise no new issues of safety and effectiveness.

BIOCOMPATIBILITY TEST RESULTS:

A complete battery of tests was carried out in accordance with the requirements of ISO 10993-1 and the FDA May 1, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing on the raw materials. Testing was performed on the Disposable set of XTRA Autotransfusion System (accelerated aging). The device was tested for Hemolysis, Hemocompatibility, Cytotoxicity, Intracutaneous Reactivity, Sensitization,. Acute Systemic Toxicity and Mutagenicity, Sterility, Pyrogenicity. ETO residuals and package integrity testing were also conducted. The results of the testing met established specifications.

IN VITRO TEST RESULTS:

Testing supplied in the 510(k) premarket notification for the XTRA Autotransfusion System includes electrical testing, electromagnetic compatibility testing, and performance testing that demonstrate compliance with performance specifications.
The results of the study showed the device characteristics between XTRA Autotransfusion System and Dideco ELECTA were comparable.

CONCLUSIONS:

The results of *in vitro* studies demonstrate that the XTRA Autotransfusion System is substantially equivalent to the predicate device in terms of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Sorin Group Italia S.r.l.
c/o Mr. Barry Sall
195 West Street
Waltham, MA 02451

OCT 5 2010

Re: K101586
Trade/Device Name: XTRA Autotransfusion System
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion apparatus
Regulatory Class: II
Product Code: CAC
Dated: September 3, 2010
Received: September 7, 2010

Dear Mr. Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Donna R. Vachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Device Name: XTRA Autotransfusion System (K101586)

Indications for Use:

The XTRA Autotransfusion System is indicated for intraoperative recovery of blood, washing of blood collected in the postoperative period, and preoperative sequestration (with indirect patient connection). Typical clinical applications of autotransfusion include the following surgical specialties:

- Cardiovascular
- Orthopedics
- Thoracic
- Transplant Surgery
- Emergency (Trauma)
- Neurosurgery
- Obstetrics and gynecology
- Urology

Prescription Use __X__ (Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vichinsky

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101586